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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,973	11/07/2006	David Louis Feldman	33687-US-PCT	3773

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/592,973	FELDMAN ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *2 and 4-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I (claims 1-4, 7-10) and election of the absence of an additional agent, and election of diabetes type 2 as the disease, in the reply filed on February 05, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, and 4-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse on the reply filed February 05, 2009. Applicant indicated that claims 1, 3, 7 and 8 read upon the elected invention however claims 7 and 8 depend from claim 5 which is withdrawn for being the non-elected species because it claims the presence of an additional agent and thus claims 7 and 8 are also withdrawn. Claims 1 and 3 are pending examination on the merits.

Applicant submitted an information disclosure statement (IDS) on November 07, 2006. Both foreign patents and non-patent literature were cited but not considered because no copy was provided. Even though the references were cited in the international search report copies must be provided and in English for them to be considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of type 2 diabetes, does not reasonably provide enablement for prevention or delay of type 2 diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant is claiming a method of preventing or delaying the progression of type 2 diabetes with a rennin inhibitor (claim 1) and specifically the compound of formula I (claim 3).

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The quantity of experimentation is undue (1) due to the lack of direction or examples towards prevention of type 2 diabetes or who is even at risk for type 2 diabetes (2,3). The nature of the invention is prevention of type 2 diabetes which is a complicated and unpredictable disease (4) and the state of the prior art is such that prevention of the disease is not known, even identifying those at risk is difficult as there are so many different ways that one can develop type 2 diabetes (5). The relative skill of those in the art is high (6) however the unpredictability of prevention of a disease such as diabetes is extremely high (7). The breadth of the claims is very large, especially claim 1 which is not limited to any specific compound but encompasses any renin inhibitor (8).

One of skill in the art at the time of the invention would not be able to use the invention as claimed without an undue amount of experimentation and thus claims 1 and 3 are rejected for lacking an enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, applicant claims a treatment for a disease selected from diabetes type 2 (associated with or without hypertension). The parenthesis are unclear as to whether this is a limitation to the claim or not and thus one of skill in the art would not be able to

determine exactly what is being claimed and claims 1 and 3 are rejected for failing to distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (US 2003/0114389 A1, cited on applicant's IDS).

In claim 1 applicant claims treatment of type 2 diabetes with an effective amount of a renin inhibitor. In claim 3, applicant claims that the renin inhibitor of claim 1 is a compound of formula I. Webb et al. teaches a composition comprising a renin inhibitor of formula I (page 1, [0001]) which is the same compound claimed, and they teach use of that compound for treatment of type 2 diabetes (page 3, [0031] and page 4, [0046]). They also teach a combination therapy of the renin inhibitor of formula I and an insulin secretion enhancer and insulin sensitizer (page 4, [0047-0052]) which would also anticipate the claims given the open language of comprising. Since Webb et al. teaches the same compound to treat the same disease, Webb et al. anticipates claims 1 and 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (US 2003/0114389 A1, cited on applicant's IDS), in view Bridon et al. (US 6,849,714) in further view of Kirpichnikov (Current Diabetes Report, 2002, Vol. 2, No. 3, pages 251-257).

As discussed above Webb et al. teaches a combination of a renin inhibitor of formula I for treatment of type 2 diabetes. They do not mention specifically if the patient had hypertension. Bridon et al. teaches that renin inhibitors are known to treat hypertension (column 19, lines 62-66). Kirpichnikov teaches that over 70% of type 2 diabetes also have hypertension (abstract) and therefore it would be obvious to one of ordinary skill in the art at the time of the invention to use the method of Webb et al. on a diabetic patient with hypertension and one of ordinary skill in the art would have a reasonable expectation for success given that renin inhibitors are known to treat hypertension. Thus claims 1 and 3 are unpatentable over Webb et al. in view of Bridon et al. in further view of Kirpichnikov et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614